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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,894	04/27/2001	Lu-Kwang Ju	5277	5277

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EXAMINER
MARX, IRENE

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,894	JU, LU-KWANG	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-104* is/are pending in the application.

4a) Of the above claim(s) *35-69 and 71-104* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-4,6-34 and 70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The application should be reviewed for errors. Error occurs, for example, in the recitation of "a port" at line 21 of claim 1.

The amendment filed 2/24/05 is acknowledged. Claims 1-4, 6-104 are presented for examination.

In the last Office action, claim 70 was inadvertently indicated as "claim 71". The confusion is regretted.

Newly submitted claims 71-104 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The claims under examination and the newly presented claims are directed to processes that are distinct from one another because they recite different and distinct conditions and steps which lead to different and distinct products.

Newly presented claims 71-104 differ from the process under examination in requiring cultivation in a medium that has a tendency to foam during aeration, requires an aeration rate such that no anti-foaming agent or apparatus is required, requires only the 'capacity of using oxygen', such that an alternative oxidant can be used exclusively for the process; there is no requirement for a maximum oxygen replenishment at aeration. In fact, aeration may be omitted. It is also uncertain that the same class, genus and/or species of microorganism is involved in the process as claimed in the claims under examination and in newly presented claims 71-104.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 71-104 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-4, 6-34 and 70 are being considered on the merits.

Claims 35-69 and 71-104 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or

Claims 1-4, 6-34 and 70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for a process wherein the process has "a maximum oxygen replenishment rate to the culture medium" and wherein the maximum oxygen replenishment rate is defined as "the maximum rate of oxygen mass transfer to the medium at any given dissolved oxygen concentration of the culture medium and any given oxygen partial pressure over the culture medium". Careful review of the written disclosure did not find basis or support for this material in the as-filed specification.

Therefore, this material constitutes new matter and should be deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-4, 6-34 and 70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing in that the term "selected" at lines 13 and 22 lacks internal antecedent basis.

Claims 1-4, 6-34 and 70 are/remain incomplete in the absence of a recovery step for the product produced.

While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. Thus, the claims fail to particularly point out and distinctly claim the "complete" process since the recovery step is missing from the claims. The metes and bounds of the claimed process are therefore not clearly established or delineated.

Claims 1-4, 6-34 and 70 are vague and indefinite in the recitation the process has "a maximum oxygen replenishment rate to the culture medium" and wherein the maximum oxygen replenishment rate is defined as "the maximum rate of oxygen mass transfer to the medium at any given dissolved oxygen concentration of the culture medium and any given oxygen partial

pressure over the culture medium", even when reading the claims in light of the specification. See the new matter rejection *supra*.

Response to Arguments

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

Applicant appears to argue that claims need only be directed to the "inventive part" of a process. However, claims are required to recite a complete process to comply with the statutes regarding the proviso of particularly pointing out and distinctly claiming the subject matter which applicant regards as his invention. Invention in this context does not pertain only to the "inventive" portion but to the invention as a while. Here there is no agreement between the preamble and the body of the claims. In claim 1 , for example, the preamble sets forth that the claim intends to accomplish "the production of a biological product" while the body of the claim is devoid of the production of any product in the process. In claim 70 the preamble is directed to "increasing concentration of a microorganism in a medium". Yet the concentration of microorganisms is not addressed in the body of the claim and there is no indication that concentration is in fact "increased" and by how much. The claims lack agreement between the preamble and the body of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly

owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 10, 16-19, 21, 28, 31-34 and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Robertson *et al.* (Appl. Environ. Microbiol., 1988. Vol. 54, pages 2812-2818).

The claims are directed to a process of making a biological product with a microorganism including bacteria, yeasts, molds and archaea in a medium containing an alternative oxidant source wherein the process has "a maximum oxygen replenishment rate to the culture medium" and wherein the maximum oxygen replenishment rate is defined as "the maximum rate of oxygen mass transfer to the medium at any given dissolved oxygen concentration of the culture medium and any given oxygen partial pressure over the culture medium" and under anaerobic conditions such that at least a portion of the population consumes said alternative oxidant at least a part of the production process.

Robertson *et al.* disclose a process of making a biological product with *T. pantotropha* wherein if the oxygen within the culture medium is less than the maximum rate of oxygen replenishment to the culture medium, the microorganisms will substantially utilize oxygen for cellular respiration, and when the oxygen requirements for cellular respiration of the strain within the culture medium is greater than the maximum rate of oxygen supply to the culture medium, then at least a portion of the microorganism concentration within the culture medium will utilize the alternative oxidant source for cellular respiration during at least a part of the production process. See, e.g., page 2814. The electron acceptors are oxygen, nitrate and/or nitrite. See, e.g., Table 3. Oxygen "replenishment" is discussed on page 2815, col. 2.

Claims 1-4, 6-34 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robertson *et al.* taken with Wendt *et al.*, Brock and Wagner *et al.*.

The claims are directed to a process of making a biological product with a microorganism including bacteria, yeasts, molds and archaea in a medium containing an alternative oxidant source wherein the process has "a maximum oxygen replenishment rate to the culture medium" and wherein the maximum oxygen replenishment rate is defined as "the maximum rate of oxygen mass transfer to the medium at any given dissolved oxygen concentration of the culture medium and any given oxygen partial pressure over the culture medium" and under anaerobic

conditions at least a portion of the population consumes said alternative oxidant at least a part of the production process.

Robertson is discussed *supra*.

The reference differs from the claimed invention in the use of *Pseudomonas* strains.

However, Wendt *et al.* disclose a process for the production of a biological product with cells of a microorganism including *Pseudomonas* (col. 4, lines 58-64) under aerobic and anaerobic conditions in the presence of alternative oxidant sources such as nitrates such that the strain uses the alternative oxidant source when the demand of oxygen exceeds the supply. See, e.g., col. 6, lines 27-60.

The reference differs from the claimed invention in that nitrate is the only oxidant or electron acceptor disclosed for anaerobic respiration. However, Brock discloses a variety of such oxidants, including fumarate, sulfate, sulfur, ferric ion and nitrite (See, e.g., pages 113-114).

The substitution of nitrate or another ion with of salts or acids as the source of the respective ion is deemed to be well within the ordinary skill in the art, particularly since the respective ions are generally provided as a salt in an aqueous nutrient medium environment.

The references further differ from the invention as claimed in the use of small acids or fatty acids in the medium. However, Wagner *et al.* adequately demonstrate that it is routine in the art to provide nutrient media containing small acids, such as malonate, succinate, pyruvate or malate, or fatty acids such as stearic acid for microorganisms, including *Pseudomonas*. (See, e.g., col. 3). The Wagner *et al.* reference also addresses the use of nutrient limitation in the cultivation of bacteria, specifically by limiting magnesium or nitrogen for the production of rhamnolipids with *Pseudomonas* (See, e.g., Examples 2-3).

One of ordinary skill in the art would have had a reasonable expectation of success in obtaining a biological product by cultivation of a microorganism in the presence of an alternative oxidant source under aerobic conditions followed by anaerobic conditions using a variety of carbon sources and the limitation of a variety of nutrients to boost yields of a desired product depending on the specific microorganism to be cultured and/or the product to be produced.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of cultivation of Robertson *et al.* by using *Pseudomonas* strains as taught by Wendt *et al.* and further by the substitution of nitrate by other

oxidants, as suggested by Brock, when the oxygen demand exceeds the oxygen supply, as well as the use of nutrient limitation and various carbon substrates, as suggested by the teachings of Wagner *et al.* for the expected benefit of maximizing the production of useful biological products produced by a microorganism suitable for use in the pharmaceutical industries and for foods or feed, for example.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

Applicant argues that the process of Wendt *et al.* fails to disclose simultaneous aerobic and anaerobic respiration as claimed by applicant. However, claims 1 and 70 as written fail to require "simultaneous aerobic and anaerobic respiration". The process as now claimed requires:

> "supplying the culture medium with a suitable amount of the alternative oxidant source that *can be used* by the selected microorganism *to permit* cellular respiration such that when the oxygen requirement for cellular respiration of the microorganism within the culture medium is less than the maximum rate of oxygen replenishment to the culture medium, the microorganism will substantially utilize oxygen for cellular respiration, and when the oxygen requirements for cellular respiration of the microorganisms within the culture medium is greater than the maximum rate of oxygen supply to the culture medium, then *at least a portion of the microorganism concentration within the culture medium will utilize the alternative oxidant source for cellular respiration*; sustaining cells in the culture medium such that at least a portion of the population consumes said alternative oxidant during at least a part of the production process
>
> (emphasis added and spelling corrected).

The claim does not require "simultaneous aerobic and anaerobic respiration" and is interpreted to indicate that aerobic and anaerobic may be sequential, since "at least a portion" includes "all".

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
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Art Unit 1651